TSR-XML Data Element Comparisons

Use the horizontal scroll bar to display hidden columns

If you don't see all four columns in the table below, scroll down to the bottom of the table and use the horizontal scroll bar to display them.

Data Fields	Sample TSR Data	Sample Corresponding XML Data	Comments
Record Verification Date	2013-03	<verification_date>2013-03< /verification_date>	NA
Trial Category	Complete	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Trial Type	Interventional	<study_type>Interventional</study_type>	NA
NCI Trial Identifier	NCI-2011-9999	<id_info> <secondary_id> <id>NCI-2011-99999</id> <id_type>Registry Identifier</id_type> <id_domain>CTRP (Clinical Trial Reporting Program)</id_domain> </secondary_id> </id_info>	NA
ClinicalTrials.gov Identifier	NCT01234567	(Not included in the XML file)	NA
Lead Organization (Trial) Identifier	CCCCWFU 12345	<org_study_id>CCCCWFU 12345</org_study_id> and <id_info> <secondary_id> <id>CCCCWFU 12345</id> <id_type>Other Identifier</id_type> <id_domain>Wake Forest University Health Sciences</id_domain> </secondary_id> </id_info>	Wake Forest University Health Sciences is the Lead Organization in this example
DCP Identifier	WFU-01-01-06	<id_info> <secondary_id> <id>WFU-01-01-06</id> <id_type>Registry Identifier</id_type> <id_domain>DCP</id_domain> </secondary_id> </id_info>	ClinicalTrials.gov captures all other identifiers as <secondary_id>
CTEP Identifier	WFU-01-01-06	<id_info> <secondary_id> <id>WFU-01-01-06</id> <id_type>Registry Identifier</id_type> <id_domain>CTEP</id_domain> </secondary_id> </id_info>	ClinicalTrials.gov captures all other identifiers as <secondary_id>
CCR Identifier	CCR-123	(Not included in the XML file)	ClinicalTrials.gov captures all other identifiers as <secondary_id>
Amendment Date	02/10/2003	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Amendment Number	35	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Type	Interventional	<study_type>Interventional</study_type>	NA
Official Title	A Phase II Double-Blind Feasibility Study of Armodafinil...	<official_title> A Phase II Double-Blind Feasibility Study of Armodafinil... </official_title>	NA
Brief Title	Armodafinil in Treating Fatigue Caused By Radiation Therapy in Patients With Primary Brain Tumors	<brief_title> Armodafinil in Treating Fatigue Caused By Radiation Therapy in Patients With Primary Brain Tumors </brief_title>	NA
Acronym	ABC	<acronym>	NA

Brief Summary	This clinical trial is studying how well Armodafinil works...	<brief_summary> <textblock> This clinical trial is studying how well Armodafinil works... <textblock> <brief_summary>	NA
Detailed Description	Detailed Description...	<detailed_description> <textblock> Detailed Description... </textblock> </detailed_description>	NA
Primary Objectives	I. To estimate...	<detailed_description> <textblock> PRIMARY OBJECTIVES: I. To estimate... </textblock> </detailed_description>	NA
Secondary Objectives	I. To obtain a preliminary estimate...	<detailed_description> <textblock> SECONDARY OBJECTIVES: To obtain a preliminary estimate... </textblock> </detailed_description>	NA
Outline	OUTLINE: This is a multicenter study...	<detailed_description> <textblock> OUTLINE: This is a multicenter study... </textblock> </detailed_description>	NA
Keywords	Feasibility Armodafinil; narcolepsy	<keyword>Feasibility Armodafinil</keyword> <keyword>narcolepsy</keyword>	NA
Reporting Dataset Method	Complete	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Sponsor	National Cancer Institute	<sponsors> <lead_sponsor> <agency>National Cancer Institute</agency> </lead_sponsor> </sponsors>	NA
Lead Organization	Wake Forest University Health Sciences	<overall_official> <first_name>Jane</first_name> <last_name>Doe</last_name> <role>Principal Investigator</role> <affiliation>Wake Forest University Health Sciences</affiliation> </overall_official>	NA
Principal Investigator	Jane Doe	<overall_official> <first_name>Jane</first_name> <last_name>Doe</last_name> <role>Principal Investigator</role> <affiliation>Wake Forest University Health Sciences</affiliation> </overall_official>	NA
Responsible Party	Sponsor	<resp_party_type>Sponsor</resp_party_type>	NA
Overall Official	Jane Doe (Principal Investigator) Wake Forest University Health Sciences	<overall_official> <first_name>Jane</first_name> <last_name>Doe</last_name> <role>Principal Investigator</role> <affiliation>Wake Forest University Health Sciences</affiliation> </overall_official>	NA
Current Trial Status	Closed to Accrual and Intervention as of 08/01/2012	<overall_status>Active, not recruiting </overall_status>	NA
Trial Start Date	08/01/2010-Actual	<start_date>2010-08</start_date> <start_date_type>Actual</start_date_type>	NA
Primary Completion Date	01/11/2014-Actual	<primary_compl_date>2014-01 </primary_compl_date> <primary_compl_date_type>Actual </primary_compl_date_type>	NA

Completion Date	02/04/2014-Actual	<last_follow_up_date>2014-02</last_follow_up_date> If no data are available, the "<last_follow_up_date>" does not appear in the XML file.	Not required for the ClinicalTrials.gov schema
Regulatory Information > Studies a U.S. FDA-regulated Drug Product	Yes	<oversight_info> <fda_regulated_drug>Yes</fda_regulated_drug> </oversight_info>	NA
Regulatory Information > Studies a U.S. FDA-regulated Device Product	Yes	<oversight_info> <fda_regulated_device>Yes</fda_regulated_device> </oversight_info>	NA
Regulatory Information > Unapproved/Uncleared Device?	Yes	<delayed_posting>Yes</delayed_posting>	NA
Regulatory Information > Post Prior to U.S. FDA Approval or Clearance	Yes	<oversight_info> <post_prior_to_approval>Yes</post_prior_to_approval> </oversight_info>	NA
Regulatory Information > Pediatric Post-market Surveillance (of a Device Product)	Yes	<oversight_info> <ped_postmarket_surv>Yes</ped_postmarket_surv> </oversight_info>	NA
Regulatory Information > Product Exported from the U.S.	Yes	<oversight_info> <exported_from_us>Yes</exported_from_us> </oversight_info>	NA
Regulatory Information > FDA Regulated Intervention?	Yes	<is_fda_regulated>Yes</is_fda_regulated>	NA
Regulatory Information > Section 801?	Yes	<is_section_801>Yes</is_section_801>	NA
Regulatory Information > DMC Appointed?	Yes	<oversight_info> <has_dmc>Yes</has_dmc> </oversight_info>	NA
Regulatory Information > IND /IDE Study?	Yes	<is_ind_study>Yes</is_ind_study>	NA
Board Approval Status	Submitted, approved	<irb_info> <approval_status>Approved</approval_status> </irb_info>	NA
Board Approval Number	IRB00012856	<irb_info> <approval_number>IRB00012856</approval_number> </irb_info>	NA
Board	Wake Forest University Health Sciences	<irb_info> <name>Wake Forest University Health Sciences</name> </irb_info>	NA
Affiliation	Wake Forest University Health Sciences	<irb_info> <affiliation>Wake Forest University Health Sciences</affiliation> </irb_info>	NA
IND/IDE > Type	IND	<ind_info>	Applies to IND and IDE
IND/IDE > Grantor	CBER	<ind_grantor>CBER</ind_grantor>	NA
IND/IDE > Number	119999	<ind_number>119999</ind_number>	NA
IND/IDE > Holder Type	NCI	(Not included in the XML file)	NA
IND/IDE > Availability of Expanded Access	Yes	<has_expanded_access>Yes</has_expanded_access>	NA
IND/IDE > Expanded Access Record	NCT12345678	<expanded_access_nct_id>NCT12345678</expanded_access_nct_id>	NA
NIH Grants > Funding Mechanism	U10	<secondary_id> <id>**U10**CA88888</id> <id_type>NIH Grant Number</id_type> </secondary_id>	NA

NIH Grants > NIH Institution Code	CA	<secondary_id> <id>U10**CA**88888</id> <id_type>NIH Grant Number</id_type> </secondary_id>	NA
NIH Grants > Serial Number	88888	<secondary_id> <id>U10CA**88888**</id> <id_type>NIH Grant Number</id_type> </secondary_id>	NA
NIH Grants > NCI Division /Program Code	DCP	(Not included in the XML file)	NA
Data Table 4 Information > Funding Category	Externally Peer-Reviewed	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Data Table 4 Information > Funding Sponsor/Source	National Cancer Institute	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Data Table 4 Information > Program Codes	2, 5, 12	(Not included in the XML file)	NA
Anatomic Site Code	Prostate	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Collaborator Name	National Cancer Institute	<collaborator> <agency>National Cancer Institute</agency> </collaborator>	Not required for the ClinicalTrials.gov schema
Collaborator Role	Funding Source	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Disease/Condition Name	Prostate Carcinoma	<condition>Prostate Carcinoma</condition>	NA
Trial Design > Type	Interventional	<study_type>Interventional</study_type> and <study_design>Interventional</study_design>	NA
Trial Design > Expanded Access	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Trial Design > Primary Purpose	Prevention	<study_design> <interventional_design> <interventional_subtype>Prevention< /interventional_subtype> </interventional_design> </study_design>	NA
Pragmatic Trial	Yes	(Not included in the XML file)	NA
Trial Design > Phase	II	<study_design> <interventional_design> <phase>II</phase> </interventional_design> </study_design>	NA
Trial Design > Interventional Study Model	Parallel	<study_design> <interventional_design> <assignment>Parallel Assignment< /assignment> </interventional_design> </study_design>	NA
Trial Design > Model Description	Lorem ipsum dolor sit amet ...	<study_design> <interventional_design> <model_description> <textblock>Lorem ipsum dolor sit amet ... < /textblock> </model_description> </interventional_design> </study_design>	NA
Trial Design > Number of Arms	2	<study_design> <interventional_design> <number_of_arms>2</number_of_arms> </interventional_design> </study_design>	NA
Trial Design > Masking	Participant, Investigator, Care Provider, Outcomes Assessor	<study_design> <interventional_design> <no_masking>No</no_masking> <masked_assessor>Yes</masked_assessor> <masked_caregiver>Yes</masked_caregiver> <masked_investigator>Yes< /masked_investigator> <masked_subject>Yes</masked_subject> </interventional_design> </study_design>	NA

Trial Design > Masking Description	Lorem ipsum dolor sit amet ...	<study_design> <interventional_design> <masking_description> <textblock>Lorem ipsum dolor sit amet ... </textblock> </masking_description> </interventional_design> </study_design>	NA
Trial Design > Allocation	Randomized Controlled Trial	<study_design> <interventional_design> <allocation>Randomized Controlled Trial </allocation> </interventional_design> </study_design>	NA
Trial Design > Target Enrollment	100	<enrollment>100</enrollment>	NA
Eligibility Criteria > Accepts Healthy Volunteers?	No	<eligibility> <healthy_volunteers>No</healthy_volunteers> </eligibility>	NA
Eligibility Criteria > Sex	Female	<eligibility> <gender>Female</gender> </eligibility>	NA
Eligibility Criteria > Gender Based	Yes	<eligibility> <gender_based>Yes</gender_based> </eligibility>	NA
Eligibility Criteria > Gender Eligibility Description	Lorem ipsum dolor sit amet ...	<eligibility> <gender_description> <textblock>Lorem ipsum dolor sit amet ... </textblock> </gender_description> </eligibility>	NA
Eligibility Criteria > Minimum Age	18 Years	<eligibility> <minimum_age>18 years</minimum_age> </eligibility>	NA
Eligibility Criteria > Maximum Age	N/A	<eligibility> <maximum_age>N/A</maximum_age> </eligibility>	NA
Eligibility Criteria > Inclusion Criteria	Family history of prostate cancer...	<eligibility> <criteria> <textblock>Inclusion Criteria: Family history of prostate cancer...</textblock> </criteria> </eligibility>	NA
Eligibility Criteria > Exclusion Criteria	Patient must not have had radiation therapy in the pelvic area...	<eligibility> <criteria> <textblock>Exclusion Criteria: Patient must not have had radiation therapy in the pelvic area...</textblock> </criteria> </eligibility>	NA
Intervention(s) > Type	Drug	<intervention_type>Drug</intervention_type>	NA
Intervention(s) > Name	Armodafinil	<intervention_name>Armodafinil </intervention_name>	NA
Intervention(s) > Alternate Name	2-(difluoromethyl)-DL-ornithine, 2-(difluoromethyl)-dl-ornithine Hydrochloride,...	<intervention_other_name> 2-(difluoromethyl)-DL-ornithine, 2-(difluoromethyl)-dl-ornithine Hydrochloride,... </intervention_other_name>	NA
Intervention(s) > Description	Given orally	<intervention_description> <textblock>Given orally</textblock> </intervention_description>	NA
Arm/Group(s) > Type	Placebo Comparator	<arm_type>Placebo Comparator</arm_type>	NA
Arm/Group(s) > Label	Arm II	<arm_group_label>Arm II</arm_group_label>	NA
Arm/Group(s) > Description	Patients receive oral Armodafinil once daily...	<arm_group_description> <textblock>Patients receive oral Armodafinil once daily...</textblock> </arm_group_description>	NA

Primary Outcome Measures > Title	Accrual rate estimated as the number of patients ...	<primary_outcome> <outcome_measure>Accrual rate estimated as the number of patients ...< /outcome_measure> </primary_outcome>	NA
Primary Outcome Measures > Description	Estimated using an analysis of covariance (ANCOVA) model which includes...	<outcome_description> <textblock>Estimated using an analysis of covariance (ANCOVA) model which includes... </textblock> </outcome_description>	NA
Primary Outcome Measures > Time Frame	Up to 2 years	<outcome_time_frame>Up to 2 years< /outcome_time_frame>	NA
Secondary Outcome Measures > Title	Incidence of toxicity incidents...	<secondary_outcome> <outcome_measure>Incidence of toxicity incidents assessed...</outcome_measure> <secondary_outcome>	NA
Secondary Outcome Measures > Description	NA	<outcome_description>	NA
Secondary Outcome Measures > Time Frame	Up to 2 years	<outcome_time_frame>Up to 2 years< /outcome_time_frame>	NA
Sub-groups Stratification Criteria > Label	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Sub-groups Stratification Criteria > Description	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Marker Name	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Evaluation Type	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Assay Type	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Biomarker Use	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Biomarker Purpose	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Specimen Type	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Participating Sites > Facility	Wake Forest University Health Sciences Winston-Salem, NC 27106 United States	<location> <facility> <name>Wake Forest University Health Sciences</name> <address> <city>Winston-Salem</city> <state>NC</state> <zip>27106</zip> <country>United States</country> </address> </facility> </location>	NA
Participating Sites > Contact	Doe, Jane, M. phone:123-123-1234 Email:jmd@domain.com	<location> <contact> <first_name>Jane</first_name> <middle_name>M</middle_name> <last_name>Doe</last_name> <phone>123-123-1234</phone> <email>jmd@domain.com</email> </contact> </location>	NA
Participating Sites > Recruitment Status and Dates	Enrolling by Invitation as of 05/09/2014	<location> <status>Enrolling by Invitation</status> </location>	NA
Participating Sites > Target Accrual	40	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Participating Sites > Investigators	Doe, Jane, Principal Investigator	<investigator> <first_name>Jane< /first_name><last_name>Doe< /last_name><role>Principal Investigator< /role> </investigator>	NA